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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,205	05/06/2004	Christopher E. Banas	6006-157	7254

7590 11/19/2010  
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EXAMINER
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GANESAN, SUBA

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
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11/19/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/840,205	<b>Applicant(s)</b> BANAS ET AL.	
	<b>Examiner</b> SUBA GANESAN	<b>Art Unit</b> 3774	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,7,9-15 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7,9-15 and 17-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/21/2010 has been entered.

### ***Response to Arguments***

2. Applicant's arguments filed 7/21/2010 have been fully considered but they are not persuasive.

3. Applicant argues that Palmaz does not disclose or suggest a plurality of microperforations disposed through a wall segment disposed between longitudinally alternating radially extending peaks and valleys. Examiner disagrees. Examiner considers the interstitial web of Palmaz to be a "wall segment" that is disposed between alternating peaks (midpoint of the highest region) and valleys (midpoint of the lowest region). This interpretation is consistent with the combination of Palmaz and Casey, as Casey teaches similar peak-to-valley configuration in fig. 4B. This broad interpretation of the terms "peak" and "valley" is consistent with Applicant's specification, where these terms must refer to the uppermost and lowermost portions of the undulating segments in order to accommodate "wall segments."

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4. Applicant's arguments with respect to Drasler are moot in view of the new grounds of rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims **1, 3, 13-14, 17-18, 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) (Palmaz) in view of Casey, II et al. (Pub. No.: US 2004/0019375) (Casey).

2. Palmaz teaches an implantable medical graft, comprising: a generally tubular body member comprising a film selected from the group consisting of metallic and pseudometallic materials (page 17, lines 1-7); and at least a portion of the body member having a plurality of circumferential corrugations defined by a radially undulating pattern of wall segments disposed between longitudinally alternating radially extending peaks and valleys (fig. 2 and 10, and page 5, lines 16-19, specifically: "the plurality of structural members may be arranged . . . [as] single or plural elements which form a tubular diamond-like or undulating pattern, in which adjacent structural members are spaced apart from open regions or interstices between adjacent structural members").

However, this teaching from Palmaz is not described in sufficient detail to warrant the conclusion that Palmaz teaches continuous circumferential corrugations with radially

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extending peaks and valleys. Casey teaches a vascular graft structure with continuous circumferential corrugations having radially extending peaks and valleys (fig. 1) resulting in a prosthetic graft with strong and flexible walls. Casey further teaches undulation-free sections (fig. 1). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the graft of Palmaz with areas of continuous circumferential undulations with radially extending peaks and valleys as suggested by Palmaz and specifically taught by Casey for the purpose of providing a strong and flexible graft wall. The need for flexibility is particularly relevant when designing for implantation within a curved vessel in the body, or when providing a minimally invasive implantation technique. Palmaz teaches several methods of fabricating the disclosed stent/graft, including deposition and etching. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to combine a thin film deposited graft with unitary structural support members as taught by Palmaz with a specific pattern of structural support (i.e. an undulating structure) as taught by Casey, since doing so would be a substitution of the structural members of Palmaz with the undulating structure of Casey, both designs arriving at the same purpose: providing a stronger graft. Such a substitution of one known equivalent element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

3. Palmaz teaches microperforations disposed through the wall segments (e.g. figs. 2-3 and 8A-C, page 12 lines 1-8). Palmaz broadly teaches that the openings “may be random or may be patterned” and are preferably located in the interstitial web 24 (see

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fig. 2). Examiner considers the interstitial web to be a "wall segment" that is disposed between alternating peaks (midpoint of the highest region) and valleys (midpoint of the lowest region). This interpretation is consistent with the combination of Palmaz and Casey, as Casey teaches similar peak-to-valley configuration in fig. 4B. Palmaz teaches non-undulating circumferential regions (see fig. 3); Casey further teaches non-undulating circumferential regions (figs. 1-5).

4. The Palmaz stent is made of a film of metallic material, including titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof (pg. 17 lines 1-7).

5. With respect to claim 17, Palmaz in view of Casey teach the circumferential corrugations as claimed. The resultant combination would be fully capable of bending in excess of 180 degrees about the longitudinal axis, since Palmaz discloses thin film deposition, which results in a thin and flexible prosthesis, and Casey teaches the use of corrugations to increase flexibility (fig. 1).

6. Claims **2, 11-12, 15, 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) (Palmaz) in view of Casey, II et al. (Pub. No.: US 2004/0019375) (Casey) further in view of Chuter et al. (Pub. No.: US 2003/0176912) (Chuter).

7. Palmaz in view of Casey is explained supra. Palmaz in view of Casey lacks suture openings on an end of the graft. Chuter teaches the use of openings 35 for

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sutures (fig. 1, for example) for the purpose of securing an end support to the graft and ultimately anchoring the prosthetic in an area with the best available tissue for anchorage. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized openings on the resultant combination device of Palmaz and Casey. A person of ordinary skill in the art would recognize that the reinforcement provided by openings 35 of Chuter would be desirable to prevent elongation or tears in the suture hole by providing a stronger location for attachment. One of ordinary skill in the art would have further been motivated to provide suture openings to provide specific placement of sutures aid a surgeon in anchoring the prosthetic to a native blood vessel.

8. Chuter further teaches the use of at least one barb member 86 to provide further anchoring of the device. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the combination of Palmaz and Casey with at least one barb for the purpose of providing additional anchorage and stabilization of the device in the body. Chuter teaches at least one suture member integrally extending along a longitudinal axis of the device: see fig. 2 for example.

9. Claims **6-7, 9-10, 21-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) (Palmaz) in view of Casey, II et al. (Pub. No.: US 2004/0019375) (Casey) and Chuter et al. (Pub. No.: US 2003/0176912) (Chuter) as applied above, further in view of Kula et al (6,325,825 B1) (Kula).

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10. Palmaz in combination with Casey and Chuter teaches an implantable medical graft as above. However the combination lacks the thickness of the undulating regions as less than that of the non-undulating regions. Kula teaches an implantable medical graft having thicker ends, which correspond to the non-undulating regions of Palmaz/ Casey (col. 4, lines 60-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of an implantable medical graft having thicker ends, as taught by Kula, to an implantable medical graft as per Palmaz/ Casey, in order to “protect the artery and any plaque from abrasion that may be caused by the stent 10 ends during insertion of the stent 10. The modification also may provide increased radio-opacity at the ends of the stent 10. Hence it may be possible to more accurately locate the stent 10 once it is in place in the body” as found in Kula (col. 4, lines 60-66).

Regarding claim 7 Palmaz/ Casey in further view of Kula fail to disclose the **specific** thicknesses of the claimed regions. However, Palmaz discloses that the thickness of the microperforated material is approximately 10 micrometers (page 21, lines 13-14). Palmaz also discloses that the circumferential corrugations may be formed by a “subtractive” method (Fig. 10). The reduction of the undulation region relative to the non-undulated region would result in a thickness of the thinner region *about* 3-7 micrometers.

11. With respect to claims 9, 10, 21 and 22 Palmaz/ Casey/Kula fail to disclose the suturing openings as cruciform, generally Y-shaped slots or elongated slots with a terminal fillet. However, at the time the invention was made, it would have been obvious



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to a person of ordinary skill in the art to make the slots these shapes. Applicant has not disclosed that these shapes provides an advantage, is used for a particular purpose, or solve a stated problem, and therefore appear to be a matter of obvious design choice. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the holes of Chuter or the claimed slots because both allow for the passage of sutures. Furthermore such shaped holes for sutures are known in the art (Moser U.S. Pat. No. 5725556). Therefore, it would have been obvious to one of ordinary skill in the art to modify the cited references to obtain the invention as specified in claims 9 and 10.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./  
Examiner, Art Unit 3774

/DAVID ISABELLA/  
Supervisory Patent Examiner, Art Unit 3774